

REMARKS

Pursuant to the present amendment, claims 21, 30 and 31 have been amended. Claims 21-24 and 30-34 are pending in the present application. No new matter has been introduced by way of the present amendment. Reconsideration of the present application is respectfully requested.

In the Office Action, claims 21-24 and 30-34 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Rose (U.S. Patent No. 3,102,356) in view of Fuchs (DE 20022306) or Hassler (U.S. Patent No. 6,997,958). Applicants respectfully traverse the Examiner's rejections.

As the Examiner well knows, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); M.P.E.P. § 2143.03.

With respect to alleged obviousness, it is necessary for the Examiner to identify the reason why a person of ordinary skill in the art would have combined the prior art in the manner claimed. The mere fact that the prior art can be combined or modified does not make the

resultant combination obvious. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01. The consistent criterion for determining obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. The suggestion cannot be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988); M.P.E.P. § 2142.

On page 4 of the Office Action, the Examiner asserted that "the claim language does not require a one to one correspondence" with respect to the neck extending out of the bore a length that corresponds to the size of the spacer(s). Applicants respectfully disagree. Independent claim 21 specifically recites "wherein the first neck is adapted to extend outwardly from said femoral head in various lengths, wherein each length corresponds to the thickness of said at least one of said plurality of spacers inserted into the bore." Independent claim 30 recites "said first neck extending outwardly from said femoral head by a length that corresponds to a thickness of said at least one spacer positioned within said internally threaded bore." Pursuant to the present amendment, the phrase "inserted" or "positioned" (depending on the claims) "within said internally threaded bore" has been added to the claims in an effort to make it even more clear that the length of the neck corresponds to the thickness of the spacer(s) within the threaded bore, as recited in the claims.

On page 3 of the Office Action, in attempting to rebut the argument that the Examiner has failed to recognize many express claim elements, the Examiner made some statement regarding the undersigned's argument being analogous to arguing that one reference lacks certain

limitations because the secondary references teach features said to be lacking. The Examiner's statement is not understood. Moreover, the argument the Examiner failed to recognize express claim limitations is simple and straightforward – no analogies are needed. In the previous Office Action and in the current Office Action, the Examiner has, respectfully, simply ignored many express claim limitations in maintaining the previous rejections.

Independent claim 21 recites, among other things, an assembly comprising a first neck and a femoral hip stem comprising a second neck having a tapered outer surface that is adapted to be positioned in the tapered, cylindrical-shaped internal bore in the first neck to thereby form a Morse taper connection. Claim 21 also recites that the first neck is adapted to extend outwardly from the femoral head in various lengths, wherein each length corresponds to the thickness of at least one of the plurality of spacers inserted in the threaded bore.

Independent claim 30 recites, among other things, an assembly comprising a first neck and a second neck having a tapered outer surface that is adapted to be positioned in the tapered, cylindrical-shaped internal bore in the first neck to thereby form a Morse taper connection. Claim 30 also recites that the first neck extends outwardly from the femoral head by a length that corresponds to a thickness of the at least one spacer inserted in the threaded bore.

Dependent claim 31 recites that the at least one spacer comprises a plurality of spacers and that the first neck extends outwardly from the femoral head by a length that corresponds to a combined thickness of the plurality of spacers inserted in the threaded bore.

It is respectfully submitted that all pending claims are readily allowable over the art of record. Respectfully, Rose does not disclose or suggest the structure set forth in the pending claims. For example, Rose does not disclose an assembly comprising the recited first and second

necks, nor does it disclose or suggest the use of the claimed spacers to determine the length by which the first neck extends from the femoral head. In Rose, in Figure 7, it is clear that the axial positioning of the neck 6 is controlled by rotating the threaded neck 6 within the threaded bore 9. Rose states “when the screw plug 16 is loosened the head can be rotated to position the same outwardly or inwardly with respect to the shoulder 5 in accordance with requirements and then when so adjusted the stem can be locked against further rotation by a clock-wise rotation of the plug 16.” Col. 2, ll. 50-55 (emphasis added). Rose is in direct contrast to the inventions set forth in the pending claims wherein the thickness of the one or more spacers controls the axial positioning or length of the first neck relative to the femoral head. As understood by the undersigned, the stop rings in Figure 5 of Rose do not operate to control the axial positioning of the neck 6. In fact, Rose only states that these stop rings “prevent relative displacement between the parts.” Col. 2, ll. 41-42. It is clear that the neck 6 in Figure 5, with the slot 11 formed therein, may be axially positioned within the head by loosening the plug 16 and positioning the neck 6 at the desired axial position to control the length thereof, as described for the embodiments depicted in Figures 3 and 4. Thereafter, inserting the screw 16 into the bore 15 of the neck 6 expands and binds against the bore 9 to secure the neck 6 in the desired axial position. Rose, Col. 2, ll. 7-42.

The citation to Fuchs and Hassler cannot cure the fundamental deficiencies in Rose. The Examiner asserts that the bottom opening in the figure of Fuchs is a tapered opening. The undersigned cannot tell from the drawing if that is true or not. Nevertheless, even assuming the Examiner's assertion is correct, the combination of Rose and Fuchs fails to disclose many

expressly claimed features of the pending claims – namely, the use of the thickness of one or more spacers to determine the femoral offset or length of the first neck.

Hassler is similarly deficient. All Hassler disclosures are purportedly new ways to make tapered connects between various components. It should also be noted that the only express disclosure of a prosthesis for a hip (Figure 10) in Hassler only shows a tapered connection between the femoral head 50 and the neck 51/tail 52 combination. Thus, the combination of Rose and Hassler likewise fails to disclose many expressly claimed features of the pending claims.

It is respectfully submitted that the assertion that the pending claims would have been obvious in view of Rose, Fuchs and Hassler is legally improper. First, even if Rose, Fuchs or Hassler were combined, that combination of art would still not teach all of the claimed limitations. Thus, such a rejection would be legally improper. Moreover, the Examiner has not identified any reason why one skilled in the art would be motivated to modify the teachings of Rose, Fuchs and Hassler to arrive at Applicants' claimed invention. The Examiner's conclusory statement (Office Action, p. 3) that it "would have been obvious to make the neck of Rose detachable so that it could be fit to different stems to better adapt the invention to the particular patient" is very troubling. First, the Examiner has offered no reasoned explanation of why one skilled in the art would be motivated to modify Rose as suggested by the Examiner. Certainly, the express disclosure of Rose contradicts the Examiner's position wherein the neck is formed integrally with the femoral stem. Second, the Examiner's statement reflects improper hindsight analysis using Applicants' disclosure as a roadmap.

A recent Federal Circuit case makes it crystal clear that, in an obviousness situation, the prior art must disclose each and every element of the claimed invention. *In re Lee*, 61 U.S.P.Q.2d 143 (Fed. Cir. 2002). Conclusory statements regarding common knowledge and common sense are insufficient to support a finding of obviousness. *Id.* at 1434-35.

In summary, it is believed that claims 21-24 and 30-34 are in condition for immediate allowance. The Examiner is invited to contact the undersigned attorney at (713) 934-4055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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